

**WE CLAIM:**

## 1. A clinical trial management system comprising:

a main database of information concerning prior clinical trials and resources available to conduct future clinical trials, the information concerning prior clinical trials being at least in part in the form of a protocol of (a) scheduled visits of a test subject to a treatment site, (b) measurement of prescribed physical attributes of the subject during the visits and (c) administration of at least one prescribed medical product to the subject during the visit to determine over time the subject's response thereto, the protocol of a prior clinical trial being stored in said main database in the form of a software template;

a main processor controlling access to said main database; and

at least one user processor in communication with said main processor to negotiate access to said main database, said user processor and main processor running a program that permits the design and tracking at said user processor of a clinical trial through access by said user processor to at least one software template in said main database and modification of the template to formulate a new clinical trial.

## 2. The clinical trial management system of claim 1 further comprising:

a subsidiary database;

a subsidiary processor controlling access to said subsidiary database, said subsidiary processor being in communication with said main processor to controlling replication of a portion of the data in the main database to said subsidiary database;

at least one subsidiary user processor in communication with said subsidiary processor, said subsidiary processor and subsidiary user processor running the program so as to permit the design and tracking at said subsidiary user processor of a clinical trial based on data in said subsidiary database.

## 3. The clinical trial management system of claim 2,

wherein said subsidiary processor, subsidiary database and subsidiary user processor are located in a certain geographical location remote from the location of said main database and said main processor; and

wherein the portion of data replicated to said subsidiary database relates to clinical trials in said certain geographical location.

## 4. The clinical trial management system of claim 3 wherein the portion of

data in said subsidiary database includes at least one template of a clinical trial protocol previously created according to requirements prevalent in the certain geographical location.

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5. The clinical trial management system of claim 3, wherein the portion of data in said subsidiary database can be altered by said subsidiary user processor and the data in the main database can be altered by said user processor; and

5 wherein said main processor and said subsidiary processor periodically operate to synchronize the replicated and changed data at said main database and said subsidiary database, with changes at said main database predominating over changes at said subsidiary database.

10 6. The clinical trial management system of claim 1 wherein said main processor and main database are in an organizational environment which includes other databases with specialized information useful in formulating clinical trials; and

further including a communications link with said other databases and means for replicating selected portions of the data in the other databases into the main database.

7. The clinical trial management system of claim 6 wherein the other databases are one of a human resources database of personnel and location information, a finance database of budget authorization and cost information and a clinical supplies database of information on the availability of various clinical medical products.

20 8. The clinical trial management system of claim 1 further including a display at the user processor which is operative to display the clinical trial protocol as a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task.

9. The clinical trial management system of claim 8 wherein said users processor can used to input information concerning completion of tasks in the protocol, and the display is updated to show progress of the trial.

25 10. The clinical trial management system of claim 9 wherein the program automatically indicates the completion of a major task when all of its minor related tasks are completed.

11. The clinical trial management system of claim 1 wherein the program is in the form of modules.

30 12. The clinical trial management system of claim 11 wherein the program includes a reports module that generates reports of the status of the trial for presentation on the display.

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13. The clinical trial management system of claim 11 wherein the program includes a reports module that generates messages to personnel concerning actions to take to advance the trial.

14. The clinical trial management system of claim 13 wherein at least one of the messages is to a provider of clinical supplies for the trial to inform it of the medical products needed for the trial.

15. The clinical trial management system of claim 3 wherein the program includes a site management module for indicating the conditions at the certain geographical location, including the portion of any protocol to be carried out in that geographical location.

16. The clinical trial management system of claim 15 wherein information about the completion of tasks in the protocol at the certain geographical location are entered by the subsidiary user processor in the subsidiary database, and the site management module updates the portion of the protocol related thereto.

17. The clinical trial management system of claim 1 further including a portable processor running the program, said portable processor operating with said main processor to transfer to the portable processor a copy of a portion of the main database related to a site for the clinical trial in a certain geographical area, said main processor locking the portion of the main database that was copied, said portable processor receiving information about the completion of tasks in the protocol at the certain geographical area and modifying the copy as a result thereof, and said portable processor operating with said main processor to transfer to and update the main database with the modified copy of the data and to unlock that portion of the main database.

18. In a hierarchical database system including a main database and main processor to govern access to it and at least one subsidiary database and subsidiary processor to govern access to it, a method of data replication to synchronize at least a portion of data in both databases, comprising the steps of:

arranging the data in both databases as rows of data in one or more tables;

deploying some tables from the main database to the subsidiary database as read-only tables;

deploying some portions of some tables from the main database to the subsidiary database which can be modified in the subsidiary database;

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tagging each row of the tables in the main database with a main or a particular subsidiary identification such that the tagged row can only be modified at the associated main or subsidiary database; and

periodically replicating modifications to data made in subsidiary databases on subsidiary tagged rows of tables to the main database, and modifications to data made in the main database on main tagged rows of tables to the subsidiary databases.

19. A clinical trial management system comprising:

a main database of information concerning resources available to conduct clinical trials;

a main processor controlling access to said main database;

at least one user processor in direct communication with said main processor to negotiate access to said main database, said user processor and main processor running a program that permit the design of a clinical trial in the form of a protocol of tasks to be completed and the tracking of the completion of the tasks in the protocol at said user processor;

a subsidiary database;

a subsidiary processor controlling access to said subsidiary database, said subsidiary processor being in communication with said main processor to controlling replication of a portion of the data in the main database to said subsidiary database;

at least one subsidiary user processor in communication with said subsidiary processor, said subsidiary processor and subsidiary user processor running the program so as to permit the design and tracking at said subsidiary user processor of a protocol based on data in said subsidiary database.

20. The clinical trial management system of claim 19,

wherein said subsidiary processor, subsidiary database and subsidiary user processor are located in a certain geographical location remote from the location of said main database and said main processor; and

wherein the portion of data replicated to said subsidiary database relates to clinical trials in said certain geographical location.

21. The clinical trial management system of claim 20 wherein the portion

of data in said subsidiary database includes at least one template of a clinical trial protocol previously created according to requirements prevalent in the certain geographical location.

22. The clinical trial management system of claim 20,

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wherein the portion of data in said subsidiary database can be altered by said subsidiary user processor and the data in the main database can be altered by said user processor; and

wherein said main processor and said subsidiary processor periodically operate to synchronize the replicated and changed data at said main database and said subsidiary database, with changes at said main database predominating over changes at said subsidiary database.

23. The clinical trial management system of claim 19 wherein said main processor and main database are in an organizational environment which includes other databases with specialized information useful in formulating clinical trials; and

further including a communications link with said other databases and means for replicating selected portions of the data in the other databases into the main database.

24. The clinical trial management system of claim 23 wherein the other databases are one of a human resources database of personnel and location information, a finance database of budget authorization and cost information and a clinical supplies database of information on the availability of various clinical medical products.

25. The clinical trial management system of claim 19 further including displays at the user processor and subsidiary user processor which are operative to display the clinical trial protocol as a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task.

26. The clinical trial management system of claim 25 wherein said user processors and subsidiary user processors can used to input information concerning completion of tasks in the protocol, and the display is updated to show progress of the trial.

27. The clinical trial management system of claim 26 wherein the program automatically indicates the completion of a major task when all of its minor related tasks are completed.

28. The clinical trial management system of claim 19 wherein the program is in the form of modules.

29. The clinical trial management system of claim 27 wherein the program includes a reports module that generates reports of the status of the trial for presentation on the display.

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30. The clinical trial management system of claim 27 wherein the program includes a reports module that generates messages to personnel concerning actions to take to advance the trial.

5 31. The clinical trial management system of claim 29 wherein at least one of the messages is to a provider of clinical supplies for the trial to inform it of the medical products needed for the trial.

10 32. The clinical trial management system of claim 19 wherein the program running on said subsidiary user processor includes a site management module for indicating the conditions at the certain geographical location, including the portion of any protocol to be carried out in that geographical location.

15 33. The clinical trial management system of claim 32 wherein information about the completion of tasks in the protocol at the certain geographical location are entered by the subsidiary user processor in the subsidiary database, and the site management module updates the portion of the protocol related thereto.

20 34. The clinical trial management system of claim 19 further including a portable processor running the program, said portable processor operating with said main processor to transfer to the portable processor a copy of a portion of the main database related to a site for the clinical trial in a certain geographical area, said main processor locking the portion of the main database that was copied, said portable processor receiving information about the completion of tasks in the protocol at the certain geographical area and modifying the copy as a result thereof, and said portable processor operating with said main processor to transfer to and update the main database with the modified copy of the data and to unlock that portion of the main database.

25 35. The clinical trial management system of claim 19 wherein there are a plurality of user processors located at different clinical trial sites in the geographical area in which the main processor and main database are located.

30 36. The clinical trial management system of claim 19 wherein there are a plurality of subsidiary processors and subsidiary databases each located in respective geographical areas that are different from the geographical area in which the main processor and main database are located.

37. The clinical trial management system of claim 36 wherein there are a plurality of subsidiary user processors located in each geographical area in which a subsidiary

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processor and subsidiary database are located, said plurality of subsidiary user processors being connected to the subsidiary processor in their respective geographical area.

38. The clinical trial management system of claim 37 in which the geographical areas are countries.

39. A data acquisition and management systems including a main database and a main processor running a program that (i) controls access to said main database, (ii) provides a plan in the form of a series of tasks for acquisition of data including major tasks and minor tasks that make up at least some major tasks, and (iii) organize data for presentation to a user,

a data input device for inputting data according to the plan,

a data display device for displaying the plan and the status of its completion, said program automatically updating the display of the plan based on data input by device such that input of data indicating the completion of a last minor task making up a major task causes said display device to indicate completion of the major task.

40. The data acquisition and management system of claim 39 wherein plan is in the form of at least one lower level plan that forms part of a higher and wherein the program automatically updates the display of the upper level plan based on the completion of tasks on the lower level plan.

41. The data acquisition and management system of claim 39 where the program said program being in the form of at least one lower level plan that forms part of a higher level plan and wherein an update in one module courses an update in another.

42. The clinical trial management system of claim 27 wherein there the plan is in the form of at least one lower level plan that forms part of a higher and wherein the program automatically updates the display of the upper level plan and where an update in a lower level plan automatically update.

43. A clinical trial management system comprising:

a main database of information concerning resources available to conduct clinical trials;

a main processor controlling access to said main database;

at least one user processor in direct communication with said main processor to negotiate access to said main database, said user processor and main processor running a program that permits the input of information with regard to the completion of tasks forming a

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protocol for a clinical trial and the tracking of the completion of the tasks at said user processor, a portion of said program printing forms determined by the data in the system.

44. The clinical trial management system of claim 43,

further including a subsidiary processor, subsidiary database and subsidiary user processor located in a certain geographical location remote from the location of said main database and said main processor; and

wherein a portion of data in the main database is replicated to said subsidiary database and relates to clinical trials in said certain geographical location.

45. The clinical trial management system of claim 19 wherein the system

manages a plurality of clinical trials with separate protocols, at least some of the separate protocols having major tasks made up of a plurality of minor tasks that are common to them, and wherein the program automatically indicates the completion of a common major task in the separate protocols when all of the minor related tasks are completed.

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